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UNITED STATES DEPARTMENT OF COMMERCE

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*Ca*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/434,708 11/05/99 BAND

H B0801/7159(E)

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HM12/0601

EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

*16*

DATE MAILED:

06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/434,708**

Applicant(s)  
**Waban et al.**

Examiner  
**G. R. Ewoldt**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 11, and 50 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11, and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-7, 9, 11, and 50 are being acted upon.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 1-7, 9, 11, and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in Paper No. 16, mailed 1/02/01.

Applicant's arguments, filed 4/09/01, have been fully considered but have not been found persuasive. Applicant argues that the specification teaches that "a Cbl-SL polypeptide binds a tyrosine kinase and regulates its expression," at page 8, line 27 - page 9, line 14 of the specification. However, said passage merely asserts the invention; said assertion is insufficient to support the claims to a nucleic acid which encodes a specific polypeptide with specific properties including *in vivo* (Claim 50) activities.

Applicant further provides a short discourse on the epidermal growth factor receptor and includes a number of references regarding said receptor's function. However, said discourse and references can not provide additional support for the invention of the instant claims because the rejections are based on insufficient guidance regarding how to make and use the polypeptides encoded by the claimed nucleic acids, and not the properties of the asserted ligand for the asserted polypeptides.

Applicant argues that the specification does provide sufficient evidence to establish that the cbl-SL protein is expressed. It is the Examiner's position that such is not the case for the reasons of record.

Applicant argues that the specification does provide for *in vivo* biological activity of the naturally expressed protein. It is the Examiner's position that such is not the case for the reasons of record, particularly in consideration of the fact that the specification provides no *in vivo* data or examples.

Applicant argues that Example 9 of the Written Description Guidelines indicates that claims to high stringency conditions should be allowable. Said Example does not, however, indicate that conditions that are disclosed as "for example" are allowable.

5. Claims 1-7, 9, 11, and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in Paper No. 16, mailed 1/02/01.

See Applicant's arguments and the Examiner's response above.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7, 9, 11, and 50 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in Paper No. 16, mailed 1/02/01.

Applicant's arguments, filed 4/09/01, have been fully considered but have not been found persuasive. Applicant argues that the term "stringent conditions" is a term commonly used in the art. While the Examiner agrees, it is the Examiner's opinion that the term has no specific definition. It is noted that Applicant argues that the term "typically" means a  $T_m$  "about" ..., thus, indicating indefiniteness. Applicant argues that Example 9 of the Written Description Guidelines indicates that claims to high stringency conditions should be allowable. Said Example does not, however, indicate that conditions that are disclosed as "for example" are allowable.

8. The following are New Grounds for Rejection necessitated by Applicant's amendment, filed 4/09/01.

9. Claims 1-3, and 50 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

"... a polypeptide that binds a tyrosine kinase and regulates its expression."

Applicant's amendment, filed 4/09/01, asserts that support for the amendment can be found in the specification at page 8, line 27 - page 9, line 14 and in the Examples. However, while the cited passages provide support for "inhibits" or "downregulates" no support for the broader "regulates" has been found.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
May 24, 2001



Patrick J. Nolan, Ph.D.  
Primary Examiner  
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